

Exhibit 90

JAMA 3/15/95

Possible Morbidity in Women From Talc on Condoms

To the Editor.—We have written this letter to alert all physicians that female partners of condom users face a health risk that is unrelated to pregnancy, the acquired immunodeficiency syndrome, or sexually transmitted diseases. This risk is due to talc, a dry lubricant present on the surface of condoms. Talc is a known sclerosing agent, which if introduced into the female reproductive tract may result in fallopian tube fibrosis with resultant infertility.¹ Of even greater concern are studies linking talc to ovarian cancer.^{2,4}

Our interest in talc arose fortuitously during a clinicopathologic study of fibrotic capsules surrounding silicone gel-filled breast implants. We found talc, an unwanted contaminant, within 70% of the capsules evaluated.³ Microscopic examination of powder on the surface of archived surgical gloves revealed that gloves manufactured before 1991 probably represented the source of talc found in implant cavities (unpublished data, Plastic Surgery Research Forum, April 1994). We also examined other health- and consumer-related latex devices and determined that condoms and dental dams were coated with varying amounts of talc, but that pacifiers and baby bottle nipples were talc free (Table).

The harmful effect of talc on human tissue was first recognized in the 1930s when postoperative granulomatous peritonitis and fibrous adhesions were causally linked to surgical glove-donning powders. Thirty years later, Saxen et al¹ reported foreign-body granulomatous peritonitis in a woman with no previous history of abdominal surgery. Particulate matter found within her peritoneal granulomas was identical to material found on the surface of condoms used by her husband. The authors concluded that material in the condom lubricant traveled upward through the fallopian tubes and became implanted within the patient's peritoneal cavity; they also predicted that condom lubricants might contribute to tubal occlusion and sterility.

A more ominous series of studies linked talc to ovarian carcinoma; talc was observed in a number of ovarian and uterine tumors as well as in normal ovarian tissue.^{2,3} It was hypothesized that deodorizing talcs placed on the perineum (or on the surface of condoms and diaphragms) reached the ovaries via ascent through the fallopian tubes.^{2,4} In support of this hypothesis, retrospective analyses demonstrated that women who used deodorizing powders on sanitary napkins, but who had

blocked tubes and/or hysterectomies, had a lesser incidence of ovarian carcinoma than women with patent tubes.⁵

Although talc is no longer used as a surgical glove-donning powder, it is still used as a surface lubricant on the majority of condoms manufactured in the United States and abroad. Remarkably, the Food and Drug Administration never addressed the issue of talc on the surface of condoms, even though they required surgical glove manufacturers to remove all talcs used in processing.

The last 10 years has seen a dramatic increase in the use of condoms. If talc contributes to ovarian carcinoma and/or fallopian tube sclerosis, we predict a significant increase in the incidence of ovarian carcinoma and infertility due to the deleterious effects of condom talc. We do not advocate abandoning condom use. To obviate the risk of talc-associated morbidity in sexually active women, we strongly urge condom distributors to eliminate all talcs used in condom manufacture.

Candace Sue Kasper, MD, PhD
Southwest Dermatopathology Consultants
P. J. Chandler, Jr, MBA, MD
Ambulatory Plastic Surgery Center
Dallas, Tex

1. Saxen L, Kassinen A, Saxen E. Peritoneal foreign-body reaction caused by condom emulsion. *Lancet*. 1963;1:1295-1296.
2. Longo D, Young R. Cosmetic talc and ovarian cancer. *Lancet*. 1979;2:349-351.
3. Henderson W, Joslin C, Turnbull A, Griffiths K. Talc and carcinoma of the ovary and cervix. *J Obstet Gynaecol Br Commonwealth*. 1971;78:266-272.
4. Harlow B, Weiss N. A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc. *Am J Epidemiol*. 1989;130:390-394.
5. Kasper C, Chandler P. Talc deposition in skin and tissues surrounding silicone gel-containing prosthetic devices. *Arch Dermatol*. 1994;130:48-53.

Letters